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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/603,222	06/26/00	EPSTEIN	M EMR-100-A-1

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QM22/0511

EXAMINER

MOHANDESI, J

ART UNIT

PAPER NUMBER

3728

DATE MAILED:

05/11/01

#8

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/603,222

Applicant(s)

EPSTEIN, MEREL

Examiner

Jila M. Mohandesi

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-- Th MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☒ The proposed drawing correction filed on 12 March 2001 is: a) ☒ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on March 12, 2001 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patent no. 6,098,319 has been reviewed and is not accepted. The terminal disclaimer has not been recorded since the application/patent being disclaimed has not been identified.
2. The declaration under 37 CFR 1.132 filed March 12, 2001 is insufficient to overcome the rejection of claims 1 and 7-8 based upon Kantro, Cherniak, Shaw, Smith and Marc as set forth in this office action because: Complementary anecdotes do not overcome evidence of anticipation and obviousness well established by the prior art. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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4. Claims 1 and 7-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,098,319. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is nothing unobvious about providing a single disc versus a plurality of discs in a kit to make the kit cheaper.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, the phrase "the disc being securable to the orthotic foot device in a plurality of incremental orientations through 360⁰ to effect a desired balance and weight distribution" is vague and indefinite. It is not clear what structure this limitation would encompass. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). Apparatus claims cover what a device is, not what a device does. *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). See MPEP 2114.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kantro (5,170,572) in view of Cherniak (3,099,267) alone, or further in view of Shaw (1,958,097), Smith (5,345,701) and Marc (5,068,983). Kantro `572 teaches substantially all the limitations of the claims. For example a substantially circular balancing disc/cushion 20 is preferably made from a polymeric foam material of high density to provide the necessary support at the gait points. The top surface and bottom surface of disc/cushion 20 can also be angularly tapered through its thickness from its forward edge rearward with respect to each other as described at column 4, lines 14-49 and column 5, lines 37-41. Note that heel cushion/disc 19 is **tapered** at about 5 degrees. It is submitted the only reasonable conclusion (by comparison of column 4, line 32 to line 46) is that cushion 20 is also exactly **tapered** as described for cushion/disc 19. Note that while Kantro `572 has chosen to use the term "cushions" for elements 19, 20 and 21, a careful review of the entire disclosure reveals that the "high density foam material" *must necessarily be sufficiently rigid* to alter the biomechanical balance and weight distribution by providing support to specific points. The structure and function, therefore, are submitted to be the same as applicant's, notwithstanding the use of the term "cushion". If for purposes of argument any doubt should subsequently be raised concerning whether the language in Kantro `572 "Polymeric foam material of a high density to provide the necessary support at the gait" at column 4, line 14-16 means that the discs will inherently will be substantially rigid. Cherniak `267 is cited to resolve that doubt. Cherniak `267 teaches that circular foot balancing devices (50, 52, 54) "may be rigid or yieldable", see column 2, lines 1-2. Therefore, it would have been obvious to one having ordinary skill in the art and in view of Cherniak `267 to make the circular

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balancing disc/cushion **20** of Kantro '572 more rigid or sufficiently rigid to ensure better support and weight distribution. The Shaw '097, Smith '701 and Marc '983 references are cited if for purposes of argument any doubt should subsequently be raised concerning the language in Kantro '572 "tapered along an axis directed at an angle" at column 4, line 46. Shaw '097 teaches an orthotic insole having angularly inclined wedge members having a transverse thickened portion **tapered** at about 3 degrees from one edge of the insole to a point beyond its longitudinal center line and restricted approximately to the portion of the insole that underlies the metatarsal heads of a superimposed foot, and another transverse thickened portion at the heel **tapered** from the opposite edge of the insole to a point beyond said center line and spaced a substantial distance from the heel end. Marc '983 teaches an insole having about a 2 degree **tapered** resilient base piece **20** adapted to conform to the foot and having a base surface and, a top surface inclined with respect to each other and a cupped periphery for accommodating the heel and extending to the arch area. Smith '701 teaches an orthotic device **20**, including a foot sole portion **30** together with a pair of correcting wedges **24** and **26 tapered** at about 4 degrees. The wedges **24** and **26** can be seen (Fig. **2b**) to change the angle of the bottom of the foot sole portion **30** relative to the ground, thus bringing the ground up to meet the soles of the patients foot. It will be appreciated that the wedges **24** and **26** can be formed at any angle, depending on the patients needs. These references both individually and collectively are representative of corrective wedge members having upper and lower surfaces angularly inclined by a small angle greater than zero (in the range of about 2 to 5 degrees) which are used with insoles and orthotics to enhance or correct biomechanical balance and weight distribution. Therefore, it would have been obvious to one having ordinary skill in the art and especially in view of each of Shaw '097,

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Marc '983 and Smith '701 to form the circular cushion member of ~~Cherniak '267~~ ^{Kantro '572} with a top surface and a bottom surface angularly inclined by a small angle greater than zero, such as in the 2-6 degree range, to further enhance or correct the biomechanical balance and weight distribution. With respect to the claims, the Shaw '097 (3 degrees), Marc '983 (2 degrees) and Smith '701 (4 degrees) references establish that the specific angle is a design choice depending on the shape and disposition with respect to the balancing foot disc/device and the routine optimization expected by one of ordinary skill in the art dependent upon the individuals biomechanical features and the desired correction and it would have been obvious over Shaw '097, Marc '983 and Smith '701 to select the angle between the upper and lower planar surfaces of the balancing device of Kantro '572 to be whatever angle is appropriate, including between about 2 to about 6 degrees. The circular balancing disc/cushion of Kantro '572 is inherently capable of being securable to the orthotic foot device in a plurality of incremental orientations.

Response to Arguments

9. Applicant's arguments filed March 12, 2001 have been fully considered but they are not persuasive.

Contrary to applicant's remarks that none of the art being applied discloses or suggests the 2-6 degrees angular relationship between the upper and lower surfaces, each of Kantra '572 (5 degrees), Shaw '097 (3 degrees), Marc '983 (2 degrees) and Smith '701 (4 degrees) teach balancing discs with 2-6 degrees angular relationship between their upper and lower surfaces as can clearly be seen by measurement of the drawings.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jila M. Mohandesi whose telephone number is 703-305-7015. The examiner can normally be reached on Monday-Friday 7:30-4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Sewell can be reached on 703-308-2126. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-305-3579 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-5648.

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JMM

May 10, 2001

A handwritten signature in black ink, appearing to read "Paul T. Sewell". The signature is stylized with a large, looped initial "P" and a cursive "Sewell".

Paul T. Sewell
Supervisory Patent Examiner
Group 3700